OSTEOMED

JUN - 2 2006

510(k) Summary

Device Proprietary Name:	OsteoMed 1st MPJ Hemi Implant System
Device Common Name:	Hemi Toe Implant
Classification Name:	KWD Prosthesis, Toe, Hemi, Phalangeal
Name of Submitter:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4600 Fax: (972) 677-4601
Contact Person:	Dawn D. Tindall
Date Prepared:	May 9, 2006

Summary:

The OsteoMed 1st MPJ Hemi Implant is a one piece implant to supplement first metatarsal phalangeal joint arthroplasty. The implant is designed to replace the distal base of the proximal phalanx and provide a smooth articular surface for the adjacent first metatarsal head. It is available in several sizes in direct per portion to the anatomic construct of the distal base of the proximal phalanx. Primary fixation is intended via a press fit bone implant interface. The OsteoMed 1st MPJ Hemi Implant is made of cobalt chromium (ASTM F-799) and may also be provided with a titanium plasma coated stem.

The OsteoMed 1st MPJ Hemi Implant System is indicated for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions; hallux valgus, hallux rigidus, and an unstable or painful metatarsophlangeal joint. OsteoMed 1st MPJ Hemi Implants are intended for single use only.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the BioPro Hemi MP Joint (K041595), the Kinetikos Medical, K2 Hemi Toe Implant System (K023770) and the Futura BioMedical Metal Hemi Toe Implant (K971047).

Due to the similarity of materials and design to the predicate devices, OsteoMed believes that the OsteoMed 1st MPJ Hemi Implant System does not raise any new safety or effectiveness issues.

OsteoMed L.P.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

Ms. Dawn D. Tindall
Regulatory Affairs
OsteoMed L.P.
3885 Arapaho Road
Addison, Texas 75001

Re: K060536
Trade/Device Name: 1st MPJ Hemi Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: May 10, 2006
Received: May 11, 2006

Dear Ms. Tindall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060536

Device Name: OsteoMed 1st MPJ Hemi Implant System

Indications for Use:

Indicated for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions: hallux valgus, hallux rigidus and an unstable or painful metatarsophalangeal joint. OsteoMed 1st MPJ Hemi Implants are intended for single use only.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(Posted November 13, 2003)

510(k) Number K060536